IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Paul C. Harris and Brian G. Richards		
Application No.:	09/817,781	Group Art Unit:	1641
Filed:	March 26, 2001	Examiner:	B. Nguyen

For: COMPENSATION FOR VARIABILITY IN SPECIFIC BINDING IN QUANTITATIVE ASSAYS

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202

on 8/12/02 Christina McSweeney
Date Signature

Christina McSweeney
Typed or printed name of person signing certificate

REPLY TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
P.O. Box 2327
Arlington, VA 22202

Sir:

Responsive to the Restriction Requirement dated July 11, 2002, the claims of Group I (Claims 1-15), drawn to a sandwich method for detecting an analyte, classified in class 435, subclass 7.1, are elected for prosecution with traverse. Applicant reserves the right to file a divisional or continuing application, or take such other appropriate action as deemed necessary to protect the invention(s) of Group II (Claims 16-18) and Group III (Claims 19-32). Applicants do not hereby abandon or waive any rights in the Group II or Group III invention.

Applicants traverse the Restriction Requirement and request that Groups II and III be considered concurrently with the claims of Group I, or alternatively, that Group II be considered concurrently with the claims of Group I.

A single art search is all that is required to identify the relevant art for Groups I, II and III. The groups share the commonality of a solid phase assay, in which an internal control is used to compensate for variability in specific binding of assay components. The methods described in each group utilize a solid phase having common features: for example, the solid phase is membrane strip comprising an application point, a contact region, a sample detection zone and a control detection zone, in which the contact region is between the application point and the sample detection zone and the sample detection zone is between the contact region and the control detection zone. The contact region has a population of particles immobilized therein; the sample detection zone has a sample detection reagent immobilized thereon; and the control detection zone has a control detection reagent immobilized thereon. In the methods described in each group, particles are moved through the membrane strip with a fluid by capillary action. In addition, in the methods described in each group, the amount of analyte of interest in a fluid sample is related to a corrected analyte-binding particle amount, which is determined from the amount of particles immobilized in the sample capture zone and the amount of particles immobilized in the control capture zone.

In view of these considerations, there is no additional search burden in combining Groups I, II and III.

Furthermore, it should be noted that the methods in Group I and Group II are both sandwich methods for detecting an analyte. Although the fluid sample is applied at a different point on the solid phase in the methods of Group I and the methods of Group II, the determination of the corrected analyte-binding particle amount for both methods utilizes the amount of analyte-binding particles in the sample capture zone and the amount of analyte-binding particles in the control capture zone, and directly correlates the corrected analyte-binding particle amount to the amount of analyte of interest in the fluid sample. Thus, Groups I and II share an additional commonality which renders it appropriate to combine Groups I and II.

In view of these considerations, reconsideration of the restriction requirement is requested.

If the Examiner believes that a telephone conversation would expedite prosecution of the application, the Examiner is invited to call Elizabeth W. Mata at (915) 845-3558 (Mountain time zone). If Elizabeth W. Mata cannot be reached, the Examiner is invited to call David E. Brook at (978) 341-0036.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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